

ATTACHMENT E		Page 1 of 2	
Becton, Dickinson and Company			
Mass Balance Calculations for SIP Application (PTE)			
Facility:	Covington, GA		
Input data:			
Ethylene oxide usage	534,000	lb/yr	Total usage based on Mass Balance
Sterilizer removal efficiency ¹	99.9%		Based on partial pressure calculation estimate
RTO efficiency, aeration	99.970%		Based on 2019 Performance Testing
RTO efficiency, vessels	99.999%		Based on 2019 Performance Testing
Product transfer time, sterilizer to aeration	5	min	
Aeration time	16	hr	
Aeration Unload time	10	min	
System 1 removal efficiency	99%		Assume 99% Based on vendor literature
System 2 removal efficiency	99%		Assume 99% Based on vendor literature
System 2 Safety Factor	4.00		Safety factor included to account for variation in future products and product density which may impact EO residuals.
Assumptions:			
Product absorption ²	0.4%		
EO degassing rate constant, k ³	0.06151	lb/hr	
Miscellaneous fugitive loss ⁴	100	lb	captured in system 1
Calculations:			
Sterilizer:			
EO into sterilizers	533,900	lb	Total usage based on Mass Balance minus miscellaneous fugitive loss
EO absorbed by product	2,135.6	lb	
EO in sterilizer not absorbed by product	531,764.4	lb	
EO exhausted to RTO from vac/air wash	531,232.6	lb	
EO exhausted to RTO from vent	531.8	lb	
Sterilizer exhaust to RTO	531,764.4	lb	
Sterilizer exhaust removed by RTO	531,759.1	lb	
Sterilizer exhaust to atmosphere after RTO	5.3	lb	
Transfer:			
			EO will off-gas from products during aeration per equation: $C = C_o e^{(-kt)}$, where C = Final EO concentration, C _o = EO concentration at time 0, k = EO degassing rate constant, and t = degassing time in hrs.
EO offgas during product transfer to aeration	0.51%		This will be captured by system one
EO offgas during product transfer to aeration	10.9	lb	
Aeration:			
EO remaining in product entering aeration	2,124.7	lb	
Offgas during aeration	62.6%		
Offgas during unloading	0.0		
EO offgas during aeration	1,330.6	lb	
To RTO during aeration	1,330.6	lb	
To RTO during aeration unload	8.1	lb	
Total aeration to RTO	1,338.7	lb	
Aeration removed by RTO	1,338.3	lb	
Aeration exhaust to atmosphere after RTO	0.4	lb	
System1:			
Into System 1	110.9	lb	
Removed by System 1	109.8	lb	
System 1 exhaust to atmosphere	1.1		
System2:			
Into System 2	3,144.0	lb	Includes System 2 Safety Factor
Removed by System 2	3,112.6	lb	
System 2 exhaust to atmosphere	31.4		
Exhausted before Modification:			
EO exhausted to atmosphere from RTO	5.7	lb	
EO Exhausted to atmosphere by system 1	110.9	lb	
EO Exhausted by to atmosphere System 2	786.0	lb	Does not include Safety Factor ⁵
Total EO exhausted to atmosphere	902.6	lb	Before Modifications
	0.5	Tons	
Exhausted after Modification:			
EO exhausted to atmosphere from RTO	5.7	lb	
EO Exhausted to atmosphere by system 1	1.1	lb	
EO Exhausted by to atmosphere System 2	31.4	lb	Does include Safety Factor
Total EO exhausted to atmosphere	38.3	lb	After Modifications
	0.019	Tons	
Note 1			
This estimates how much EO is removed during post exposure vacuum washes but does not include what is in the product at the time it transfers to Aeration			
Note 2			
Estimates the amount of EO in the product when it starts the transfer to aeration			
Note 3			
An estimate based on Product EO Residue Testing performed by BD laboratory personnel.			
Note 4			
An estimate of potential EO emissions from pump/valve packaging, flange losses, EO supply drum changes, and non-routine losses.			
Note 5			
The Safety Factor is only included in the After Modification calculations as this insures the new System is designed to account for variation in future products and product density which may impact EO residuals.			